# UNITED STATES DISTRICT COURT WESTERN DISTRICT OF MICHIGAN SOUTHERN DIVISION

THE WILLIAM M. YARBROUGH FOUNDATION and ZANFEL LABORATORIES, INC.,

Plaintiffs,

-vs-

Case No. 06-0348 Hon. AVERN COHN

RITE AID CORPORATION, CADE LABORATORIES, LLC., and CADEY O'LEARY.

Defendants.

### **DECISION ON CLAIM CONSTRUCTION**

#### I. Introduction

This is the Markman<sup>1</sup> part of a patent case involving U.S. Patent No. 7,008,963 (the '963 patent) issued to William M. Yarborough on March 7, 2006 and assigned to the William M. Yarborough Foundation. The subject matter of the patent is Urushiol Induced Contact Dermatitis Solution.<sup>2</sup> Generally, it is for a solution used to treat the dermatitis caused by plants containing urushiol, such as poison ivy and poison oak

Plaintiffs, the inventor and assignee, accuse defendants of infringing the '963 patent.

Defendant Cade Laboratories, LLC., manufactures the accused product. Defendants Ride

<sup>&</sup>lt;sup>1</sup>See Markman v. Westview Instruments, 517 U.S. 370 (1996). See also <u>The Sedona Conference Report on the Markman Process</u>, June 2006 Public Comment Version, available at www.thesedonaconference.org.

<sup>&</sup>lt;sup>2</sup> "Solution" and "composition" are used interchangeably in the written description and claims to describe the patented product.

Aid Corporation and Cadey O'Leary are charged with contributory infringement.

The <u>Markman</u> issues have been fully briefed. The Court heard argument on June 28, 2007.

The briefs go well beyond the parties' differences in construction of disputed claim language and comes close to arguing validity and infringement. For example, defendants argue against the Court looking at the accused product, citing Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473 (Fed. Cir. 1998). Plaintiffs responds with the observation in Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1327 (Fed. Cir. 2006), that knowledge of the accused product can serve as an important contextual basis for the claim construction analysis. However, nothing the pros and cons of the argument on claim construction ties into a consideration of the accused product.

As the Court has repeatedly observed, claim construction in a <u>Markman</u> proceeding is always tentative and its conclusions are open to change as the case unfolds in the validity and infringement phases; so too here.

II. The '963 Patent

A.

The Abstract of the '963 patent reads:

A solution for urushiol induced contact dermatitis is provided for in a topical solution. According to the invention, a method is provided for applying a composition of substances to the affected area, and removing the composition from the affected area. The composition comprises at least one ethoxylate in combination with a supporting agent. It is believed that this combination binds to the available urushiol receptors rendering it inactive. The affinity of the receptors for the ethoxylates also appears to cause a release of the uroshiol from its epidermal bonds for bonding to the composition. An inert scrubbing agent, such as polyethylene beads, can also be included to

assist in the release of the urushiol. Acetylated lanolin alcohol, EDTA, a foam stabilizer, and water can also be added to the composition without effecting performance.

The Field of The Invention as described in the '963 patent reads:

The present invention relates to solutions for allergic dermatitis and more particularly to a solution for *Toxicodendrom* dermatitis, which results from contact with the *Rhus* oleoresin, urushiol.

The Objects of The Invention as described in the '963 patent reads:

It is an object of the present invention to provide a solution for urushiol induced allergic dermatitis (*Toxicodendron dermatitis*), the solution providing almost immediate and permanent relief in usually one solution.

It is a further object of the present invention to provide such a solution that utilizes a composition that chemically attaches to available urushiol receptors to block its allergic reaction properties and to release the urushiol so that it can be removed from the skin.

It is a yet further object of the present invention to provide a solution that is safe to use.

It is yet another object of the present invention to provide a solution for urushiol induced allergic dermatitis that is topical, can be purchased over the counter and is economical.

The Summary of The Invention as described in the '963 patent reads:

The above objects of the invention are provided for in a topical solution for use in urushiol induced contact dermatitis. According to the invention, a composition of substances is applied to and worked into the affected area. The solution is permitted to stay on the affected area a sufficient amount of time such that the solution has bonded with the urushiol, and the solution-urushiol complex is removed from the affected area. A secondary effect of the solution is that it interacts with the C fibers of the nervous system to provide itch relief.

The composition comprises at least one ethoxylate in combination with a compatible wetting agent, for non-limiting

example, Sodium Lauroyl Sarcosinate (or SLS). It is believed that this combination creates an urushiol-complimentary polar substance that binds with available urushiol receptors rendering it inactive. The affinity of the receptors for the ethoxylates also appears to cause a release of the urushiol from its epidermal bonds creating a micelle with the inventive solution. An inert scrubbing agent, such as polyethylene beads or pumice, can also be included to assist in the release of the urushiol. Acetylated lanolin alcohol, EDTA, a foam stabilizer, water and other various agents can also be added to the composition without effecting performance.

B.

Claim 1 of the '963 patent, which includes all of the disputed claims language reads (with the disputed language underlined):

1. A method for treating urushiol induced contact dermatitis, comprising steps of:

providing an aqueous topical composition comprising nonoxynol-9; sodium lauroyl sarcosinate; and water; applying the composition to an affected area;

permitting the composition to remain on the affected area a sufficient amount of time to enable the composition to cause an effect; and

removing the composition from the affected area.

III. Parties' Proposed Constructions

The parties proposed construction of the disputed claim language is set forth in the Joint Comprehensive Claim Construction Issues filed December 29, 2006 as follows:

Disputed Claim Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
1. Preamble	Limiting	Non-Limiting
2. Sodium lauroyl sacrosinate	The chemical compound represented by the chemical structure:	The chemical compound generally identified by CAS No. 137-16-6
3. Affected Area	An area affected by urushiol induced contact dermatitis	An area of skin with urushiol present, without regard to any physical manifestation
4. Effect	A change brought about by the composition, including for example, relief from the symptoms of urushiol induced contact dermatitis, micelle formation and urushiol binding.	The binding of the product with the urushiol on the skin so that the bound urushiol and product can be rinsed off

At oral argument, defendants accepted plaintiffs' construction of "sodium lauroyl sacrosinate"; it is no longer disputed claim language.

### IV. The Law

The law regarding claim construction is well known and needs little comment. Claim construction is an issue of law to be decided by the Court. Markman v. Westview Instruments, Inc., 517 US 370 (1996). Claim construction begins with the claim itself, moves to the written description and prosecution history and then, if necessary extrinsic evidence. Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005) (en banc). A claim is to

be construed and understood by a person of ordinary skill in the art. <u>Id</u>. at 1314.

The parties do not discuss who is a person of ordinary skill in the art and confine themselves to the claim language, written description, and file history.

Here the two ambiguous limitations "affected area" and "effect" are commonly understood words. As one commentator has explained:

In those cases where the ordinary meaning of a clear term as understood by a person of ordinary skill in the art is readily apparent event to lay persons the ordinary meaning becomes the acquired meaning of the term.

Herbert F. Schwartz, <u>Patent Law and Practice</u>, §5.I.A.2 (5<sup>th</sup> ed.) (citing, inter alia, Phillips, <u>supra</u> at 1312. Another commentator has similarly stated:

Dictionaries and similar references. A court should attempt to determine the ordinary meaning of the words used in a claim before consulting the written description and prosecution history, using dictionaries, encyclopedias, and treatises that were publicly available at the time the patent issue. Such references are objective resources that serve as reliable sources of information on the established meanings that would have been attributed to the terms of the claims by those of skill in the art. Indeed, these materials may be the most meaningful sources of information to aid judges in better understanding both the technology and the terminology used by those skilled in the art to describe the technology. Categorizing them as "extrinsic evidence" or even a "special form of extrinsic evidence" is misplaced.

Robert L. Harmon, <u>Patents and the Federal Circuit</u>, § 6.1(a)(I) (7<sup>th</sup> ed).

V. Court's Construction

A. The Preamble: A Method for Treating Induced Contact Dermatitis

Plaintiffs take the position that the preamble represents an affirmative limitation on claim 1 while defendants take the position the preamble does not limit claim 1 because it merely recites the intended use and purpose of the claimed invention. This is an inversion of the usual positions of the inventor and the putative infringer: the inventor looks for a

broad interpretation so that the claim can capture a wide range of alleged infringing products while the putative infringer looks for a narrow interpretation to escape the scope of the claim.

This difference between the parties needs no extended discussion. The examiner initially rejected a claim drawn to "methods for treating contact dermatitis" stating "only claims reciting methods for treating urushiol induced contact dermatitis were acceptable." See Px 7 - File History - at p. 20866-67 (Office Action mailed July 14, 2004). As filed, the preamble reads "a method for treating contact dermatitis." Following a rejection by the examiner, the preamble was amended to read "a method for treating urushiol induced contact dermatitis." As argued by plaintiffs in their opening Markman Brief:

Reading the claim of the '963 patent to indiscriminately cover treatment of all types of contact dermatitis would impermissibly ignore the Patent Office's rejection and Yarborough's deliberate decision to amend his claim in response.

While the significance of the parties' differences on the preamble escapes the Court, the preamble breathes life, meaning and vitality into the claim by making clear the purpose of the invention. See Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1333 (2003) ("The preamble . . . is a statement of the intentioned purpose for which the method must be performed."). Bristol-Meyers Squibb Co. v. BenVenue Laboratories, Inc., et al., 246 F2d 1368 (2001), cited by defendants' post-argument, does not persuade the Court otherwise. It may well be that plaintiffs' infringement argument or defendants' defense to infringement may require reconsideration of this issue.

<sup>&</sup>lt;sup>3</sup> Px represents the exhibits in the Appendix in Support of Plaintiffs' Opening Markman Brief.

#### B. "AFFECTED AREA"

The competing constructions of the phrase "affected area" are overdrawn.

Plaintiffs urges the construction of "affected area" as that part of the skin which comes into contact with urushiol at the point in time that the skin displays an outward manifestation of the contact, arguing that the inventor's goal was the treatment of a manifestation of contact dermatitis. Implicit in this construction is the fact that the solution would not be applied to the skin until a rash develops.

Plaintiffs' attempt to impose a limit on the time of application of the solution to the skin is not tenable.<sup>4</sup> As defendants note, the inventor's statement in the written description supports a finding that there is no temporal element to the phrase, stating:

Solution has historically consisted of attempting to remove the oil as quickly <u>after exposure</u> as possible; applying rubbing alcohol, washing <u>affected areas</u> with water, and showering with soap and water. In many instances, however, people either fail to fully remove the toxin before it has bound to the skin or don't realize they have been exposed until after the rash appears.

(col 2 II 40-46) (emphasis added). Moreover, there is nothing in the written description that suggests application of the composition begins with a manifestation of the effect of the urushiol on the skin. Rather, application of the solution may begin as soon as there is an awareness of the skin contacting the urushiol. Indeed, as noted above, an object of the invention is to provide a solution to "block" urushiol's "allergic reaction." Defendants are correct in stating that "no dermatitis-like breakout is required in the patent claim or patent

<sup>&</sup>lt;sup>4</sup> Indeed, if this was the case, no one would carry the solution with them when they went for a walk in the woods for example to apply at the time of contact, and would instead wait to apply the solution when a rash develops.

specification and the term 'affected area' should not be construed to require such physical manifestation in order to define the area."

"Affected area" is not a term of art and its ordinary meaning is well understood. The American Heritage Dictionary of the English Language defines "affected" as "acted upon" and "area" as "a distinct part."

"Affected area" simply means the area of the skin which comes into contact with urushiol.

## C. "EFFECT"

Plaintiffs in support of their construction of "effect" point to the description in the written language of the '963 patent of what occurs when the product called for by the claim comes into contact with the urushiol "... the solution ... bond[s] with the urushiol ... " and "a secondary effect . . . is that [the solution] interacts with the C filters of the nervous system . . . " (col.3, II 62-67).

Defendants' construction of "effect" is more restrictive and goes beyond the "effect" of the composition on the skin to describe what occurs as the urushiol penetrates the skin.

Again, the Court is in the dark of the consequences of the differences between the competing constructions.

"Effect" is not a technical term. There is no indication that the inventor intended to give any special meaning to the word. The American Heritage Dictionary of the English Language defines "effect" as "the way in which something acts upon or influences an object."

"Effect" simply means the consequences described in the specification which follow on the application of the composition to the affected area.

## VI. Claim Chart

Accordingly, the following is the claim construction which governs further proceedings in this case:

Disputed Claim Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction	Court's Construction
1. Preamble	Limiting	Non-Limiting	Limiting
2. Sodium lauroyl sacrosinate	The chemical compound represented by the chemical structure:  H  H  C  H  H  C  H  H  H  H  H  H  H	Agreement with plaintiffs' proposed construction	
3. Affected Area	An area affected by urushiol induced contact dermatitis	An area of skin with urushiol present, without regard to any physical manifestation	The surface of the skin which comes into contact with urushiol
4. Effect	A change brought about by the composition, including for example, relief from the symptoms of urushiol induced contact dermatitis, micelle formation and urushiol binding.	The binding of the product with the urushiol on the skin so that the bound urushiol and product can be rinsed off	The consequences described in the specification which follow on the application of the composition to the affected area.

Dated: July 24, 2007

s/Avern Cohn

AVERN COHN

UNITED STATES DISTRICT JUDGE

I hereby certify that a copy of the foregoing document was mailed to the parties of record on this date, July 24, 2007, by electronic and/or ordinary mail.

<u>s/Julie Owens</u>
Case Manager, (313) 234-5160